

AA Licence Number	Product Name	Active Ingredient/s	Source Country Authorisation Number	Source Country	Applicant	Objections Received	Status of application	Reason for decision	Conditions included in the Licence
AA1106/00603	Mycoskin Cream 1%	Ciclopirox olamine	34009 266 152 77	France	Laboratoires Bailleul S.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA770/04002	Tazorex Pdr for Soln for Injection 4/0.05g	Piperacillin Tazobactam	38053/10	Greece	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA1161/00203	Bromazepam Arena Tablets 3mg	Bromazepam	2475/2010/01-06	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1598/00101	Bupivacaine/Adrenaline Physan Solution for Injection 2.5mg/ml/0.005mg/ml	Bupivacaine hydrochloride Epinephrine	45.668	Spain	Laphysan S.A.U	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/122201	Broncovaleas Nebuliser Solution 5mg/ml	Salbutamol	AIC 22991057	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1207/00402	Prednidelt Rectal Suppositories 30mg	Prednisone	OGYI-T-5179/03	Hungary	Biotech GmbH Magyarországi Fióktelepe	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA565/19307	Synacthen Solution for Injection 250 micrograms	Tetracosactide Hexaacetate	6094745.00.01	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/02203	Fyton Pdr for Soln for Injection 15mg	Sodium-phytate	OGYI-T-9288/01	Hungary	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/94903	GRANOCYTE Pdr+Solv for Soln for Inj 13 million IU/ml	Lenograstim	34009349 756-77	France	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/11901	Aciclovir Oral Suspension 200mg/5ml	Aciclovir	PA22697/001/001	Ireland	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/00507	Phenytoin Labesfal Solution for Injection 250mg/5ml	Phenytoin sodium	3537594	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/00408	Levodopa/Benserazide Teva Capsule 200mg/50mg	Levodopa Benserazide	34009 383 295 99	France	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1389/00102	Pulmihal implantation suspension 200mcg	Budesonide	123978/08-12-2022	Greece	MEDICAIR BIOSCIENCE LABORATORIES CY LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA729/24403	Glycerin Microlysma for Babies/Zarmpi Enema 1.8g	Glycerin	43572/10	Greece	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA1601/00101	Lactulose AIWA Oral Solution 670mg/ml	Lactulose	83926.00.00	Germany	T & D Pharma GmbH	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/95902	Methylprednisolone Hikma Pdr for Soln for Injection 500mg	Methylprednisolone	AIC 042331064	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/67402	Acitretin Orifarm Capsules Hard 10mg	Acitretin	33560/ 53202	Finland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA115/02802	Zobral Tablet, film coated 5mg	Levocetirizine dihydrochloride	21149	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/91602	Ronic Eye Drops Solution 1mg/ml	Dexamethasone phosphate	3232691; 5838164	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/05201	Fluticasone Furoate Teva Nasal Spray Suspension 27.5mcg	Fluticasone furoate	PA1986/126/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/39201	ESTRAMON Transdermal Patch 25gg/24 hrs	Estradiol hemihydrate	36424.02.00	Denmark	Cherubino Ltd	Nil	Refused	Product is already authorised in Malta	N/A
AA729/39202	ESTRAMON Transdermal Patch 50gg/24 hours	Estradiol hemihydrate	36424.00.00	Denmark	Cherubino Ltd	Nil	Refused	Product is already authorised in Malta	N/A
AA729/39203	ESTRAMON Transdermal Patch 100gg/24 hours	Estradiol hemihydrate	36424.01.00	Denmark	Cherubino Ltd	Nil	Refused	Product is already authorised in Malta	N/A
AA1470/00204	Buscopan Coated Tablets 10mg	Hyoscine Butylbromide	PA23180/016/002	Ireland	Opella Healthcare France SAS,	Nil	Refused	The correct regulatory procedure is to submit a variation not a new application	N/A
AA1597/00101	Golden eye Eye Drops Solution 0.1% w/v	Propamidine isetionate	PA 22695/001/001	Ireland	Cambridge Healthcare Ireland Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA032/02705	Dexamed Tablets 0.5mg	Dexamethasone	19974	Cyprus	Medochemie Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1174/00503	Atomoxetina Generis Capsules Hard 18mg	Atomoxetine Hydrochloride	5738315	Portugal	Generis Farmacêutica, S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1416/00501	Ketokaps Max Capsules, Soft 50mg	Ketoprofen	26036	Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1454/04901	Mirap Distab Orodispersible Tablet 15mg	Mirtazapine	PA0711/094/001	Ireland	Prohealth	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	N/A
AA1454/04902	Mirap Distab Orodispersible Tablet 30mg	Mirtazapine	PA0711/094/002	Ireland	Prohealth	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	N/A

AA1438/13001	Heparin Gilvasan Solution for Inj/Inf 1000 IU/ml	Heparin sodium	1-12600	Austria	NM Pharma Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/23802	Dioralyte Natural Powder for Oral Solution 0.47g	Sodium Chloride Ph. Eur. Potassium Chloride Ph. Eur. Glucose Ph. Eur. Disodium Hydrogen Citrate B.P.	PA1113/026/001	Ireland	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1411/12001	Mysoline Tablets 250mg	Primidone	RVG00379	Netherlands	EJ Busuttil Ltd	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA565/118201	Aethylum Chloratum Filofarm 70g	Ethyl chloride	R/2106	Poland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A